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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,646	07/19/2005	Johannes Fridolin Schlapfer	8932-1208-999	1676

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 09/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/542,646	Applicant(s) SCHLAPFER ET AL.	
	Examiner Jerry Cumberledge	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>07/19/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

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- (I) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the limitation "the casing" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 18 recites the limitation "the last case" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 8-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Justis et al. (US Pub. 2002/0013586 A1).

Justis et al. disclose an apparatus for the dynamic stabilization of bones or bone fragments, in particular spinal vertebrae, with at least one longitudinal support (Fig. 3, ref. 22) that can be fixed to the vertebrae, characterized in that the at least one longitudinal support is so constructed that by application of a prespecified bending force it can be plastically deformed from a first stable shape state into a second, alternative stable shape state but while in the first as well as in the second state remains flexible within predetermined limits (paragraph 0034 and paragraph 0055). The material used in the apparatus, although elastically deformable, would become plastically deformed if bent beyond its capacity (paragraph 0055, lines 11-15). Therefore the material in the apparatus is both elastically deformable and plastically deformable. The longitudinal support is such that when clamped at one end, while within a stable shape state it can be elastically deflected by an angle of 5 degrees to 12 degrees (paragraph 0055, lines 11-15), in particular about 8 degrees (paragraph 0055, lines 11-15), over a length corresponding to the spacing of two adjacent vertebrae (paragraph 0009, lines 6-9) or about 2 to 5 cm.

The longitudinal support is constructed so as to be stable, i.e. unyielding, both with respect to anatomically usual longitudinal shear forces and with respect to anatomically usual transverse shear forces. There is a large range of "usual" forces that the body is subject to, from very small, nearly negligible forces, to relatively large forces. The plate can be considered stable when these small forces are involved. The longitudinal support is constructed so as to be substantially stable with respect to torsion. As with the other types of forces, torsional forces can have a large range, from

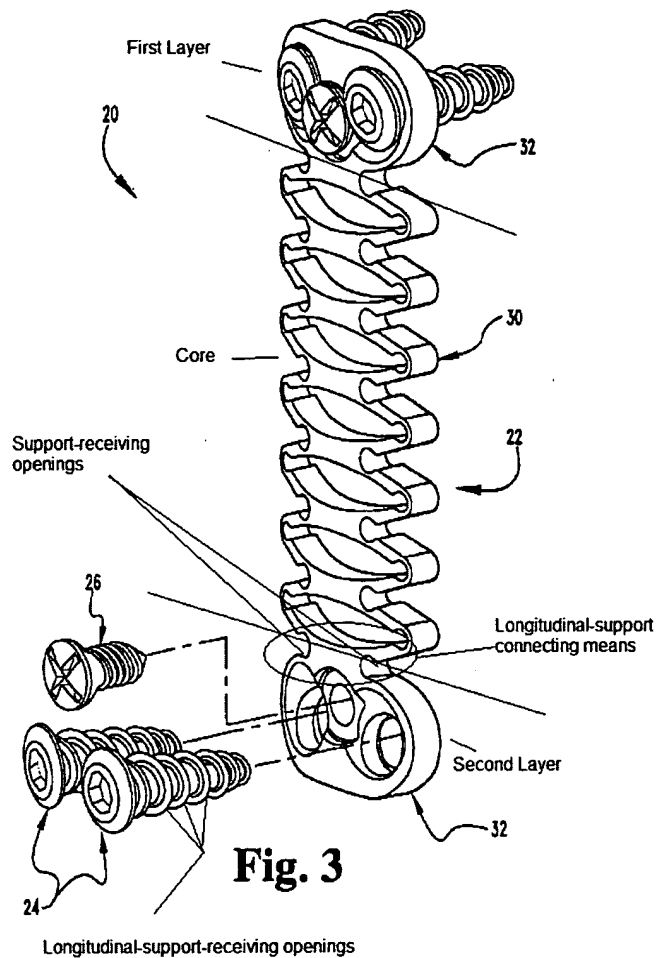
the very small to the relatively large. The plates would be stable when very small forces are involved.

The longitudinal support is constructed in the shape of a flat band or strip (Fig. 3, ref. 22). The longitudinal support is constructed so as to be rotationally symmetrical (paragraph 0031, lines 6-10). The longitudinal support comprises an in particular plastically deformable core (paragraph 0036, lines 1-5) (Fig. 4a, ref. 30) made of metal (paragraph 0035, lines 1-5) in particular titanium or a titanium alloy (paragraph 0035, line 4), which is encased in a human-tissue-compatible plastic (paragraph 0035, line 5 and paragraph 0032, lines 20-24), in particular one that ensures flexibility within a stable shape state (paragraph 0055, lines 10-15). The longitudinal support is so dimensioned that within the elastic flexion range its surface stress is always below the dynamic breaking stress. In the case of a longitudinal support core, both the core and the casing are dimensioned such that in the elastic flexion range the surface stress of both core and casing is always below the respective dynamic breaking stress. The elastic flexion range for any material is always less than the stress required to fracture or break the material and therefore the apparatus of Justis et al. has this property also.

The core is encased in more than one layer (Fig. 3 below). The apparatus comprises bone-anchoring means, in particular pedicle screws (Fig. 2, ref. 24), to which the longitudinal support or supports can be fixed. The apparatus comprises longitudinal support connecting means (Fig. 3 below), which can be used to connect at least two support sections to one another. The longitudinal-support-connecting means comprise two oppositely situated support-receiving openings (Fig. 3 below), into each of which an

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end section of the support can be inserted and fixed by way of a clamping screw or similar clamping element. The bone-anchoring means comprise longitudinal-support-receiving openings (Fig. 4a, ref. 54) that can be spaced at variable axial distances from the opposite distal end, so that the longitudinal support can be adjusted to a correspondingly different distance from the vertebra (Fig. 4a, and Fig. 4b). The core is constructed in the form of a flat band or strip (Fig. 11a, ref 32), with a width smaller than or equal to the corresponding dimension of the longitudinal support (Fig. 4b). The core is rotationally symmetrical (Fig. 12 and Fig. 13, ref 302), in particular circular (Fig. 12 and Fig. 13, ref 302), with either a constant diameter (Fig. 13, ref 302) or a diameter that varies along the length of the longitudinal support. The diameter of the core, at least in sections, is continually enlarged or reduced and/or altered in a stepwise manner (paragraph 0037, lines 1-15) such that in the last case the transitions in the region of a step are constructed so as to reduce stress, in particular are rounded (paragraph 0037, lines 12-15).



Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Sekiguchi et al. (US Pat. 5,482,029).

Unsworth et al. disclose an apparatus for the dynamic stabilization of bones or bone fragments, in particular spinal vertebrae, with at least one longitudinal support (Fig. 24, ref. 401) that can be fixed to the vertebrae, characterized in that the at least one longitudinal support is so constructed that by application of a prespecified bending

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force it can be plastically deformed from a first stable shape state into a second, alternative stable shape state (column 21, lines 46-51), but while in the first as well as in the second state remains flexible within predetermined limits. The material is still flexible when in the two configurations, since it is still within the superelasticity range (column 21, line 51).

The longitudinal support is constructed as a hollow rod (Fig. 24, ref. 401)

With regard to statements of intended use and other functional statements (e.g. ...can be spaced... can be adjusted...) they do not impose any structural limitations on the claims distinguishable over the apparatus of Justis et al. or the apparatus of Unsworth et al., which are both capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER